

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY <b>PANAMA</b>	2. DATE OF BIRTH			2a. AGE <b>55</b> Years	3. SEX <b>Male</b>	3a. WEIGHT <b>Unk</b>	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION  <input type="checkbox"/> PATIENT DIED  <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION  <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY  <input type="checkbox"/> LIFE THREATENING
		Day	Month	Year				Day	Month	Year	
			<b>PRIVACY</b>					<b>Unk</b>			

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)  
 Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)  
**abnormal results for cholesterol [Blood cholesterol abnormal]**  
**abnormal results for glucose [Glucose abnormal]**  
**abnormal results for triglycerides [Triglycerides abnormal NOS]**  
 The patient mentioned not using Enbrel continuously./ When the psoriasis starts to flare up, I go to the doctor so he can prescribe it / last month I finished a round, and now I have gone a month without using it [Intentional misuse in dosing frequency]

Case Description: This is a spontaneous report received from a Consumer or other non HCP, Program ID: 164974.

(Continued on Additional Information Page)

## II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) <b>#1 ) Enbrel (ETANERCEPT) Solution for injection in pre-filled syringe</b> <b>#2 ) Enbrel (ETANERCEPT (DEVICE CONSTITUENT)) Solution for injection in pre-filled syringe</b>		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) <b>#1 ) 50 mg, weekly</b> <b>#2 )</b>	16. ROUTE(S) OF ADMINISTRATION <b>#1 ) Unknown</b> <b>#2 ) Unknown</b>	
17. INDICATION(S) FOR USE <b>#1 ) Psoriasis (Psoriasis)</b> <b>#2 ) Psoriasis (Psoriasis)</b>		21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) <b>#1 ) Unknown</b> <b>#2 ) Unknown</b>	19. THERAPY DURATION <b>#1 ) Unknown</b> <b>#2 ) Unknown</b>	

## III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates                      Type of History / Notes                      Description <b>Unknown</b>		

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER <b>Pfizer S.A.</b> <b>Laura Arce Mora</b> <b>Avenida Escazú, Torre Lexus, piso 7. Escazú</b> <b>San jose, COSTA RICA</b>		26. REMARKS
	24b. MFR CONTROL NO. <b>PV202500082213</b>	
24c. DATE RECEIVED BY MANUFACTURER <b>07-JUL-2025</b>	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	
DATE OF THIS REPORT <b>10-JUL-2025</b>	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

25b. NAME AND ADDRESS OF REPORTER  
 NAME AND ADDRESS WITHHELD.  
  
 NAME AND ADDRESS WITHHELD.

10-Jul-2025 15:39

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

A 55-year-old male patient received etanercept (ENBREL), (Batch/Lot number: unknown) at 50 mg weekly for psoriasis. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: BLOOD CHOLESTEROL ABNORMAL (non-serious), outcome "not recovered", described as "abnormal results for cholesterol"; BLOOD GLUCOSE ABNORMAL (non-serious), outcome "unknown", described as "abnormal results for glucose"; BLOOD TRIGLYCERIDES ABNORMAL (non-serious), outcome "unknown", described as "abnormal results for triglycerides"; INTENTIONAL PRODUCT MISUSE (non-serious), outcome "unknown", described as "The patient mentioned not using Enbrel continuously/ When the psoriasis starts to flare up, I go to the doctor so he can prescribe it / last month I finished a round, and now I have gone a month without using it". Relevant laboratory tests and procedures are available in the appropriate section. The action taken for etanercept was unknown. Therapeutic measures were taken as a result of blood cholesterol abnormal.

Additional information: the physician prescribed medication for cholesterol. Then, 45 days later, the patient repeated laboratory test and results were still abnormal. The physician stated the abnormal values were expected due to sugar and fat intake, the patient stated he consumed a lot of fats. The patient had been using etanercept for 3 years. The patient mentioned not taking it while his psoriasis was somewhat controlled. When his psoriasis started to flare up he went to the physician, who would give him 4 units, once a week for a month. The patient mentioned not using Enbrel continuously. The patient finished a round in May2025 and now had gone a month without using it. The patient went back to the physician and got a prescription because he was getting some scaly patches on his skin

No follow-up attempts are possible. Batch/lot number is not provided, and it cannot be obtained.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Blood cholesterol	abnormal	
		45 days after start of cholesterol treatment		
2		Blood cholesterol	abnormal	
3		Blood glucose	abnormal	
4		Blood triglycerides	abnormal	